

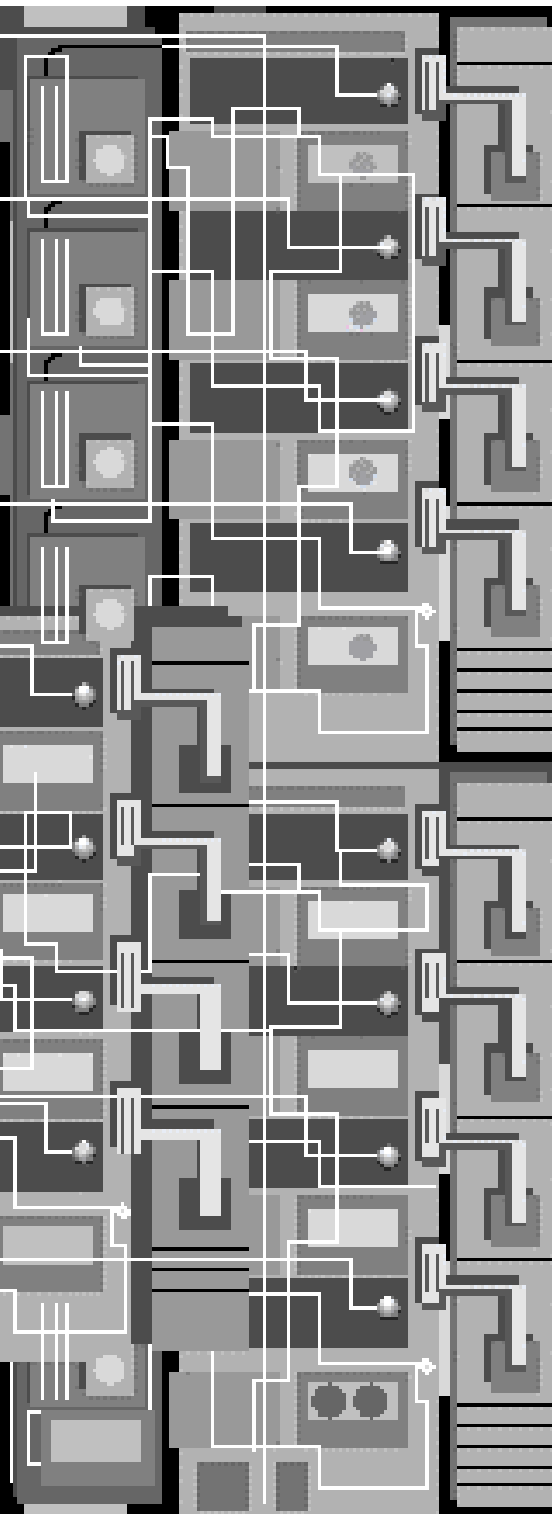
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OMB #: 0910-0408  
Expiration: 11/30/1999

# Y2K Assessment Survey

Center for Biologics  
Evaluation and Research  
US Food and Drug Administration

**June 1999**



**Y2K Assessment Survey**  
**Center for Biologics Evaluation and Research**

OFFICE USE  
ONLY

Company Name: \_\_\_\_\_

Company Address: \_\_\_\_\_  
\_\_\_\_\_

License Number or Registration/CFN Number(s): \_\_\_\_\_  
\_\_\_\_\_

Name, Title, Phone Number and Email address of Y2K Coordinator (or contact):

Y2K Coordinator (contact): \_\_\_\_\_

Title: \_\_\_\_\_

Phone Number: (    )    -   

Email Address: \_\_\_\_\_

Do you do business (i.e. distribute your products) under another business name?

- ☐ YES (PLEASE RECORD NAME AND ADDRESS)  
☐ NO

Other Business Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

1. Does your organization have a plan for addressing the Y2K problem? ☐ YES  
☐ NO

- A. Have you taken all steps necessary to ensure that the information technology and automated systems (e.g., manufacturing, quality control, in-house distribution systems) used in the facilities responsible for producing all your FDA-regulated products are Y2K compliant\*? **Please update us when any significant change in your status occurs.**

- ☐ YES (SKIP TO QUESTION 2)  
☐ NO



What date do you anticipate completing this task?

DATE.....    -    -     
MM DD YY

*\*Compliant means that the automated systems can accurately process date/time data (including, but not limited to, calculation, comparing, and sequencing) from, into, and between the years 1999 and 2000 and perform leap year calculations. This includes identifying all of the systems and correcting and validating any solutions to the problems related to Y2K or implementing workarounds to deal with the problems. In addition, you should have written documentation (e.g., assessments, test results, reports from independent reviewers) to demonstrate that all possible steps have been taken to make the systems compliant or have written documentation of your workarounds.*

2. Have you initiated or do you plan to initiate an independent review of your Y2K program (i.e., by a group other than the one who did the initial analysis)?
- ☐ YES    ☐ NO **(SKIP TO QUESTION 3)**
- ↓

A. When will this independent review be completed?

DATE .....   -   -

MM                  DD                  YY

3. Do you have foreign suppliers of materials (e.g., raw materials, equipment) used in the manufacture of your products?
- ☐ YES    ☐ NO **(SKIP TO QUESTION 4)**
- ↓

A. Have you asked these foreign suppliers about their Y2K readiness?

☐ YES **(SKIP TO QUESTION 4)**  
☐ NO

↓

When will this task be completed?

DATE .....   -   -

MM                  DD                  YY

4. Do you have contingency plans (i.e., a plan to deal with potential problems such as problems in obtaining raw materials or in manufacturing, packaging, labeling, or distributing the finished product)?
- ☐ YES **(SKIP TO 4A AND ANSWER 4A, 4B, AND 4C)**  
☐ NO
- ↓


When do you expect to have one in place?

DATE .....   -   -


MM                  DD                  YY

**(SKIP TO QUESTION 4B, 4C)**

- A. Where appropriate, have the components of the contingency plans been tested?
- ☐ YES  
☐ NO
- ↓
- When do you expect to complete testing?
- DATE .....   -   -
- MM                  DD                  YY
- B. Do the contingency plans address potential problems with your key business partners (suppliers, vendors, and distributors)?
- ☐ YES  
☐ NO
- C. Do your contingency plans address potential problems with foreign suppliers (e.g., establishment of alternate suppliers of materials)?
- ☐ YES  
☐ NO

5. Do you have plans to increase production of your products if you face an anticipated increase in consumer demand due to Y2K concerns? ☐ YES ☐ NO
- A. In response to an expected increase in demand due to Y2K concerns on the part of consumers or actual production or supply problems, is an increase in production feasible at this time (i.e., as of the second quarter of 1999)? ☐ YES ☐ NO
6. Do you anticipate submitting supplements to address any Y2K manufacturing changes? ☐ YES ☐ NO  
*This question is being asked to help us develop plans for dealing with a potential increase in the number of supplements that may be submitted for review.*
7. Do you have an Internet site that provides information on the Y2K readiness of your company? ☐ YES ☐ NO (SKIP TO QUESTION 8)
- 

A. URL? \_\_\_\_\_

8. Do you have a telephone number or other means to handle inquiries from your customers on your Y2K status? ☐ YES ☐ NO
- 

A. Telephone number? (     )    -

\_\_\_\_\_  
**President/CEO/Blood Establishment Director**

\_\_\_\_\_  
**Date**

*Please note: If your survey response includes information about registered divisions or subsidiaries, please identify these divisions and subsidiaries on a separate sheet and submit this with the survey responses.*

**Thank you for your time in completing this survey.  
If you have further questions, you may contact  
Jennifer Thomas, CBER/OCBQ Associate Director for Policy, at (301) 827-6190.**

**Please return this completed survey *and any attachments* to us  
in the enclosed pre-addressed, postage-paid envelope or if you prefer,  
fax to: 1-888-574-1327.**

**FDA Y2K Survey  
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St. Louis, MO 63132 – 9709**